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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,993	04/04/2002	Pierre Etienne Chabrier de Lassauniere	427.057	5815

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EXAMINER	
ANDERSON, REBECCA L	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,993	CHABRIER DE LASSAUNIERE ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-35* is/are pending in the application.

4a) Of the above claim(s) *33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-32,34 and 35* is/are rejected.

7)☒ Claim(s) *26-31,34 and 35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No._____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 26-35 are currently pending in the instant application. Claims 26-32, 34 and 35 are rejected, claim 33 is withdrawn from consideration as being for non-elected subject matter and claims 26-31, 34 and 35 are objected.

Election/Restrictions

Applicant's election with traverse of Group I wherein Y is O and Ω is OR48 in the reply filed on 28 March 2006 is acknowledged. The traversal is on the ground(s) that the oxazole and thiazole are equivalents. This is not found persuasive because as seen by classification, the oxazole and thiazole are classified in different subclasses of class 548. Additionally, the technical feature corresponding to the claims is the method of treatment comprising administering to warm-blooded animals an analgesically effective amount of a compound of the formula (I)3. This technical feature is not a special technical feature because it fails to define a contribution over the prior art as can be seen by US Patent No. 3,770,755, which discloses heterocyclic compounds (column 1) such as 2-(4-chlorophenyl)-4-(2-hydroxyethyl) thiazole (columns 4 and 9), which corresponds to applicants formula (I)3 wherein Y is S, A is phenyl substituted with Z, R19, R20 and R21 wherein Q is H, one of R19, R20 and R21 is halogen and the others are hydrogen, n is 1, R1 and R2 are hydrogen and W is OR48 wherein R48 is hydrogen. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications

in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

The requirement is still deemed proper.

Claim Objections

Claims 26-31, 34 and 35 are objected to as containing non-elected subject matter. Claims 26-31, 34 and 35 presented drawn solely to the elected invention as identified supra would overcome this objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-32, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, newly added claim 26 has introduced new matter into the claims as the "amount of a compound of the formula (I)3 sufficient to treat Parkinson disease" is not found in the originally filed disclosure. Applicants' amendment has introduced new matter as nowhere in the originally filed disclosure is there mention of what amount of the compound of the formula (I)3 would be sufficient to treat Parkinson disease, nor is there any examples or direction to the treatment of Parkinson's disease with any amount of the formula (I)3. The

administration dose envisaged for a medicament on page 70, does not provide direction, motivation, or support for the instant claim language. Claims which change the scope relative to the originally filed claims may lack written description, see In re Ruschig, 371 F.2d 990, 154 USPQ 118 (CCPA) 1967) which supports that the original disclosure of a large genus did not support a later filed claim to a previously unnamed single species. Furthermore, Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir.2000) notes that with respect to In re Ruschig, that "Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say "here is my invention". In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure." The only written description in Applicants' originally filed claims is for a blanket administrative does and no direction or disclosure of a dose for the treatment of Parkinson's disease is found and therefore fails to have written description and is considered new matter.

Claims 26-32, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention of claims 26-32, 34 and 35 is the treatment of Parkinson's disease. The nature of the invention of claim 35 is the treatment of Parkinson's disease, Alzheimer's disease, Huntington's chlorea, amyotropic lateral sclerosis and peripheral neuropathies.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face.

The instant claimed invention is highly unpredictable as discussed below: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize

that in regards to therapeutic effects of disorders, whether or not the disease is effected by inhibiting monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels would make a difference.

It is the state of the art that in spite of the extensive studies performed on postmortem substantia nigra from Parkinson's disease patients, the aetiology of the disease has not yet been established (Mandel, 730) and despite the success obtained with animal models, clinical neuroprotection is much more difficult to accomplish. Additionally, animal models of Parkinson's disease may not be totally reflective of the disease and a single drug may not be adequate to induce neuroprotection (Mandel 730). Additionally, major consideration should be given to the optimal time at which to initiate the neuroprotective attempts and it must be aimed at the preclinical stage of the disease of which our ability to identify is currently very limited (page 752). The general failure to induce neuroprotection in the clinic versus in the laboratory with currently available drugs suggests that a single drug would not be sufficiently active and/or that the animal models we are employing are not truly representative of the disease state (page 752).

It is the state of the art that there is no known cure or prevention for Alzheimer's disease and that there are only four medications available in the United States available to temporarily slow the early stages of Alzheimer's disease. The current drugs for the treatment of Alzheimer's disease, Aricept, Exelon, Reminyl and Cognex, treat early stages of Alzheimer's disease by delaying the breakdown of acetylcholine. Memantine, which blocks excess amounts of glutamate treats late stage Alzheimer's disease.

(URL:http://www.cnn.com/2003/HEALTH/conditions/09/24/alzheimers.drug.ap/index.html).

Hence, in the absence of a showing of correlation between all the disorders claimed as capable of treatment one of skill in the art is unable to fully predict possible results from the administration of the compound of formula (I)3 due to the unpredictability of the role of the inhibiting monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels, and since the treatment of Alzheimer's disease is mediated by the breakdown of acetylcholine or the inhibition of excess amounts of glutamate and the treatment of Parkinson's disease does not appear to be adequate with one drug.

The amount of direction or guidance present and the presence or absence of working examples

The only direction and guidance present in the specification is a list of disorders on pages 1, 2 and 69 that applicant considers treatable by inhibiting monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels and bond reactions on pages 171-174. There is no correlation between inhibiting monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels with any disorder let alone Alzheimer's disease or Parkinson's disease and the specification does not provide any pharmaceutical data for the treatment of any specific disorder, i.e. the specification is silent and fails to provide guidance as to what diseases are mediated by inhibiting monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels. There no other guidance or direction present as to

what diseases can be treated and there is no guidance as to how these diseases can be treated.

The breadth of the claims

The breadth of the claims is the treatment of Parkinson's disease and, in claim 35 the treatment of Parkinson's disease, Alzheimer's disease, Huntington's chlorea, amyotropic lateral sclerosis and peripheral neuropathies.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what disorders would be benefited by the inhibiting monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels and would furthermore then have to determine which of the claimed compounds would provide treatment of the disorder.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of the formula (I)3 for the treatment of disorders administering the compound of the formula (I)3. As a result necessitating one of skill to perform an

exhaustive search for which disorders can be treated by what compounds of formula (I)3 in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which disorders can be treated by the compound encompassed in the instant claims, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 recites the limitation "selected from the group consisting of Parkinson's disease, Alzheimer's disease, Huntington's chlorea, amyotropic lateral sclerosis and peripheral neuropathies in "the method of claim 34 wherein the disorder." There is insufficient antecedent basis for this limitation in the claim as there is no "a disorder" in claim 34. Claim 34, as in claims 26-33, is only claiming the method of treatment of Parkinson's disease.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 34 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 30 of copending Application No. 11/256901. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Specifically, claim 34 and conflicting claim 30 both claim the same species of compounds, such as 2-[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-4-oxazoleethanol.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ

645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-33 and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 122-27 and 30 of copending Application No. 11/256901. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Applicants' instant claims are drawn to the treatment of Parkinson's disease with the formula (I)3 such as 2-[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-4-oxazoleethanol.

Conflicting claims 22-27 and 30 are for the treatment of Parkinson's disease with compounds of the formula (I)3 wherein Ω is OR48 or NR46R47. Preferences are found in the claims wherein Ω is OR48, see claim 30 which claims the compound 2-[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-4-oxazoleethanol which anticipates applicants' instantly claimed invention. As the conflicting claims generically overlap with applicants'

claimed invention and provide preferences towards applicants' claimed invention with specific species which anticipate applicants' claimed invention, applicants' instant claims are rejected under provisional obviousness type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 8, 2006

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